

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-1251V

UNPUBLISHED

ANNE ZARATSIAN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 23, 2022

Special Processing Unit (SPU);
Findings of Fact; Site of Vaccination
Tetanus, Diphtheria, acellular
Pertussis (Tdap) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

*Howard Dale Mishkind, Mishkind Kulwicki Law Co., L.P.A., Cleveland, OH, for
Petitioner.*

Rachelle Bishop, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On April 19, 2021, Anne Zaratsian filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), as defined in the Vaccine Table, after receiving the tetanus, diphtheria, acellular pertussis (“Tdap”) vaccine on September 9, 2020. Petition at 1, ¶¶ 2, 4, 12.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the Tdap vaccine was most likely administered in Petitioner's left deltoid, as alleged.

I. Relevant Procedural History

Not long after the case's initiation, Ms. Zaratsian filed the affidavit and medical records required under the Vaccine Act to support her claim. Exhibits 1-3, ECF Nos. 1, 7; see Section 11(c). On October 15, 2021, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims (the "SPU")). ECF No. 11.

On December 6, 2021, Petitioner was ordered to file any additional records indicating the site of vaccination – information which was lacking on the filed vaccine record. ECF No. 14. In response, Petitioner provided a letter from her primary care provider, dated on December 22, 2021, indicating that Petitioner received the Tdap vaccine intramuscularly in her *left* deltoid on September 9, 2020. Exhibit 4, filed Dec. 27, 2021, ECF No. 17. After Respondent's counsel questioned the sufficiency of this letter, Petitioner provided a second letter, containing a more detailed accounting of the facts surrounding the vaccination. Exhibit 5, filed May 22, 2022, ECF No. 21 (letter dated May 19, 2022).

In response to an email communication from the OSM staff attorney assisting me on this SPU case, the parties confirmed that they did not wish to add any further evidence or briefing regarding the situs issue. See Informal Remark, dated Aug. 8, 2022. The matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner received the vaccination alleged as causal in her injured *left* deltoid, as alleged.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy

evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.” *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. “Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), aff'd *per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions.” *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of

the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); see also *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make these findings after a complete review of the record, which includes all medical records, affidavits, and additional evidence filed. Specifically, I highlight the following:

- Prior to vaccination, Petitioner suffered from common illnesses and conditions. Exhibit 2 at 6-213. In 2020, Petitioner was also being seen routinely by medical treaters because she was pregnant with her third child. *Id.* at 68 (listing two prior births).
- While still pregnant on September 9, 2020, Petitioner received the Tdap vaccine alleged as causal. Exhibit 2 at 214, 226. The vaccine record provides the date, type, lot number, and method of administration (intramuscularly) of vaccination and individual administering it. The record does not identify the site of vaccination. *Id.*
- Approximately two weeks post-vaccination on September 21st, Petitioner called her primary care provider (“PCP”), complaining of shoulder pain after receiving the Tdap vaccine on September 9th. Exhibit 2 at 232. She indicated that her pain began “that same day and . . . has not subsided.” *Id.* The location of Petitioner’s pain was listed as the “injection site.” *Id.* at 234; accord. *id.* at 236. Petitioner indicated that when she received vaccination, “the nurse stuck her twice because the first time was too high/needle wasn’t working.” *Id.* at 236. She requested a referral for treatment of this injury. *Id.* at 232.
- The next day on September 22nd, Petitioner was seen by her PCP for pain at the injection site of her left arm/shoulder. Exhibit 2 at 239. Reporting the

same account of being stuck twice, Petitioner added that the nurse administering the vaccine was shaky and injected the vaccine “near [the] top of [the] shoulder joint.” *Id.* Petitioner was assessed as having acute pain of the left shoulder and pain at the injection site. *Id.* at 240. After checking with her obstetrician, Petitioner was prescribed a Medrol dose pack. *Id.* at 246.

- At her prenatal visit the next day on September 23rd, Petitioner reported arm soreness from the Tdap vaccine she received two weeks earlier. Exhibit at 256.
- An ultrasound of Petitioner’s left shoulder was performed on September 23rd. Exhibit 2 at 265-67. Despite normal results, the nurse practitioner reviewing the ultrasound opined Petitioner was suffering from an injury caused form of tendinitis, rather than any chronic issues. *Id.* at 269. Petitioner was instructed to take the oral steroids prescribed by her PCP the previous day. *Id.* at 270.
- The next day on September 24th, Petitioner remotely attended an appointment with the nurse practitioner. Exhibit 2 at 272. Her left shoulder pain was again attributed to her Tdap vaccination, and the same detailed history of the administration – including two attempts and a too-high injection, was included in this record. *Id.*
- On September 25th, Petitioner was seen by an orthopedist for “left shoulder pain after receiving a TD vaccine.” Exhibit 2 at 281. She again reported achiness which began with her Tdap vaccine and progressively worsened thereafter. *Id.* at 279. She received a second cortisone injection. *Id.* at 281, 284-87.
- Petitioner reported that her left shoulder pain was gradually improving during a remote appointment on September 30, 2020. Exhibit 2 at 291
- A few days after giving birth on October 30, 2020, Petitioner inquired by phone, for additional treatment of her shoulder pain. Exhibit 2 at 570 (call on November 6 2020. She indicated that the second cortisone injection was wearing off, and she did not want to wait too long before pursuing additional treatment. *Id.*

- On December 2nd, Petitioner participated in a remote orthopedic appointment for her left shoulder pain. Exhibit 2 at 617. The next day, she attended a physical therapy evaluation. Exhibit 3 at 36. Petitioner continued PT through mid-April 2021. Exhibit 3 at 4 (last PT session on April 14th).
- In her affidavit, executed on April 17, 2021, Petitioner indicated that she received the Tdap vaccine in her left deltoid on September 9, 2020, when visiting her obstetrician. Exhibit 1 at ¶ 3.

The above medical entries show that, when seeking treatment for her left shoulder pain, Petitioner consistently attributed her pain to the Tdap vaccine she reported receiving in her left arm. She provided these histories to her PCP, obstetrician, and orthopedist. While originating from Petitioner, these statements are memorialized in contemporaneous records, and should therefore be afforded greater weight than any subsequent assertion or witness statement. The Federal Circuit has stated that “[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions.” *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, and even though the record in question simply memorializes what the petitioner said at the time, its contemporaneous nature makes it somewhat more trustworthy than after-the-fact witness statements prepared in connection with this matter.

The vaccine record clearly establishes that Petitioner received a Tdap vaccine on September 9, 2020. Thereafter, when seeking medical care for her left shoulder pain, Petitioner consistently attributed the source of her pain to the Tdap vaccine she described as improperly administered in her left deltoid. There is a dearth of evidence that the vaccine was administered in any other location. I thus determine, based on the record as a whole, that preponderant evidence establishes that the Tdap vaccine to which Petitioner attributes her SIRVA was most likely administered in her left deltoid on September 9, 2020.

V. Scheduling Order

I expect the HHS review in this case to be completed in late 2022. While awaiting the review, Petitioner should finalize a demand and should convey the demand, along with any supporting documentation, to Respondent.

Petitioner shall file any updated medical records and a status report regarding her demand, supporting documentation, and current condition by no later than Wednesday, September 28, 2022.

Respondent shall file a status report providing his tentative position regarding the merits of Petitioner's claim or, at a minimum, an updated estimate of the timing of the HHS review and assessment of the completeness of the supporting documentation for any conveyed demand by no later than Friday, October 28, 2022.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master